Re: Comments on the Draft Recommendation Statement: Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults

To Whom it May Concern:

On behalf of NASTAD, a leading non-partisan non-profit association that represents public health officials who administer HIV and hepatitis programs in the U.S., we are writing to provide comment on the United States Preventive Services Task Force’s (USPSTF) Draft Recommendation Statement: Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults.

While we are supportive of the USPSTF’s recommendation in general, NASTAD does have some concerns. NASTAD is grateful that a grade B recommendation was granted, and it will play a critical role in removing barriers and increasing access to screening and treatment for hepatitis B (HBV). However, a grade A recommendation would have provided additional attention to HBV infection as a significant threat to public health, particularly in light of its intersection with the ongoing opioid epidemic. **We urge USPSTF to expand its recommendation to universal screening of all adults with a grade “A” in order to close major gaps in identifying the 65% to 75% of undiagnosed cases in the U.S.**

We offer the following evidence and viewpoints for consideration.

**Limited Effectiveness of Current Screening Strategies and Progress in Diagnosis Rates**

The current USPSTF risk-based screening recommendation that has been in place for nearly six years (and 10 years since the Centers for Disease Control and Prevention’s HBV risk-based screening guidelines) have had limited effectiveness and progress in decreasing the prevalence of HBV infections. It is estimated that about 2.2 million people are living with HBV infection in the United States, yet a significant majority -- about 65-
75% of those, remain undiagnosed.\textsuperscript{1} Both the prevalence of HBV infection and unknown diagnosis rates far exceed those of other infectious diseases with USPSTF universal adult screening recommendations; this includes HIV infection, which affects an estimated 1.1 million people, with 14% undiagnosed.\textsuperscript{2}

Additionally, risk-based screening strategies increase potential labeling, anxiety and stigma of individuals and communities. It is important to consider that a targeted screening strategy of those labeled as high risk for HBV infection, which includes foreign-born individuals who face multiple barriers to health care access, exacerbates stigma and discrimination for already marginalized communities. Moving to universal screening of all asymptomatic adults is the best way to reduce labeling associated with infectious diseases, as has been demonstrated by population-based screening for HIV infection.

\textbf{In the U.S., rates of HBV-related mortality including hepatocellular carcinoma are on the rise.} Hepatitis B continues to be the leading cause of primary liver cancer, which is the second leading cause of cancer deaths worldwide. According to the 2020 Annual Report to the Nation on the Status of Cancer, while overall cancer incidence rates are leveling off, the incidence of liver cancer increased by 2.5% overall and by 3.5% in women, the largest increase in incidence of any cancer between 2012-2016. Additionally, liver cancer was the fifth most common cause of cancer death for men overall and death rates continue to increase among women overall.\textsuperscript{3} A strategy for universal screening for HBV infection is key to improving diagnosis, linkage to care and treatment, decreasing rates of liver cancer incidence and mortality.

\textbf{Risk-based screening for HBV infection is not routinely implemented in health care systems and places the burden on under-resourced health departments and community-based organizations.} Risk-based screening recommendations that are based on country of birth and stigmatizing risk behaviors are difficult to implement and face many challenges that often cannot be implemented within health care systems in the U.S. Targeted HBV screening strategies are implemented primarily through community-based settings by smaller and often under-resourced community-based organizations and clinics; these strategies are not sustainable in the long term. While this approach reaches persons at high risk for infection, outreach has been challenging and misses a substantial proportion of the populations considered at high risk for HBV infection. At the community level, not only are there challenges in screening communities that are hard to reach, but the asymptomatic nature of HBV infection presents an additional barrier to the demand for screening.

Hepatitis programs within jurisdictional health departments are substantially underfunded and often lack full-time employees and extensive resources to support HBV screening. In a recent state health department needs assessment conducted by NASTAD, jurisdictions reported having on average one to two full time equivalent (FTE) staff, or less, per hepatitis program area (e.g. prevention and immunization/perinatal hepatitis B), with the exception of surveillance which in many jurisdictions

\textsuperscript{2} https://www.cdc.gov/hiv/basics/statistics.html
\textsuperscript{3} https://seer.cancer.gov/report_to_nation/
receives no federal funding. Respondents noted that ideally, each program would have at least three full time staff to support successful viral hepatitis programs and services. All respondents to the assessment indicated a need to increase FTEs with a desire for 100% of their time devoted to hepatitis programs, since currently a large portion of hepatitis FTEs split their time across communicable disease programs. The reimbursement that these recommendations will allow for are a substantial step toward increasing screening in clinical and other settings given the currently limited resources available to support screening programs in health departments.

USPSTF’s decision to endorse expanded adult screening with a grade B recommendation will also allow for reimbursement for state and local health departments and their partners, opening the door for expanded screening and leading to more accurate data on infection rates and greater linkage to care.

**Targeted screening is difficult to implement in hospitals and health care systems where there is little provider awareness and incentive.**

Data from a recent analysis of community-based HBV testing events with over 3,000 persons in Philadelphia screened, reveal that almost half (46.1%) of those who tested positive for HBV infection already had a regular source of care. Yet, despite the current USPSTF recommendations and known risk factors, these individuals were not screened for HBV infection in the primary care setting. Risk-based testing for HBV puts great burden on clinicians, who are typically unaware of the risks, are unsure of who to test, and overburdened in primary care settings to learn the intricacies of who to test. There are not many incentives for providers to change their clinical patterns.

Additionally, electronic clinical decision support technology which can assist providers in identifying high-risk patients is extremely challenging to integrate. For example, electronic health records currently do not capture country of birth which is one of the major factors for those at high risk for HBV infection. Instituting electronic Clinical Decision Support faces its own challenges – current risk-based HBV screening has a complexity of risk determination – institutions have difficulty implementing electronic data collection and flags based on country of birth. Electronic health records used by most health systems do not include a field for country of birth. Nor does it include information about parental infection or parental HBV risk. It is even difficult to identify behavior risks – as patients are often hesitant to share stigmatizing factors such as sexual and drug use behaviors. All of this makes it complicated for clinicians to figure out who is at risk, making risk-based screening guidelines difficult to implement.

**There are substantial gaps in risk-based testing for HBV infection and missed opportunities to identify persons vulnerable to infection and improve hepatitis B vaccination coverage among adults.**

Reported state HBV prevalence data has revealed gaps in the risk-based screening strategy and have missed high-risk groups. The opioid epidemic and injection drug use in the U.S. have substantially increased the incidence of hepatitis B infection. Spikes in HBV infection rates range from 56% to

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457% in states most heavily affected by the opioid epidemic, including in Kentucky, Tennessee, West Virginia, North Carolina, and Maine. Studies also show a high prevalence of HBV infection among the homeless population, seven to 10 times higher than in the U.S. general population, revealing significantly lower screening rates than for HIV. There are clearly gaps in targeted screening approaches; with a universal screening strategy, we will ensure all health care and other settings for public health interventions have the incentive and resources to identify infected individuals and vaccinate those adults who are vulnerable to infection.

Cost-Effectiveness of Routine Screening
We urge the Task Force to review evidence related to the cost-effectiveness of HBV screening, including screening followed by immunization or treatment. There are several studies that have focused on the cost effectiveness of HBV screening. These studies indicate that screening is cost effective in populations where HBV prevalence is as low as 0.3%, well below the prevalence of hepatitis B surface antigen (HBsAg) of two percent or greater as noted in the assessment of risk.

We encourage USPSTF to review the U.S. Health and Human Services’ Health Resources and Services Administration’s Uniform Data System and data from federally qualified health centers that have adopted universal HBV screening of adults into their practice. Hepatitis B screening, vaccination, and treatment data from these datasets may present models for effective expansion into the larger health care system.

As a final note, we are also cognizant of the need for a sustained fight against the stigma surrounding HBV infection. Universal adult screening for HBV is an important step in the right direction, but fighting stigma and discrimination is as important in fully combating the spread of the disease, as is making structural change. Currently, thirteen states criminalize people living with viral hepatitis, including laws that treat transmission of the virus as a felony subject to severe penalties. Prosecuting people living with HBV only creates fear and spreads misconceptions of risk which further stigmatizes and exacerbates the spread of the disease. USPSTF should acknowledge the importance of clinicians being knowledgeable about the legal consequences that can accompany awareness of one’s HBV status, in some states, and also note the critical role clinicians can play—alongside policy makers, legislators, and others—to retract punitive legislation related to infection with HBV.

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Thank you for the opportunity to comment on these draft recommendations and your continued work in combating hepatitis B. We welcome the opportunity to work with you on this very important and timely issue. Should any questions arise or if you need additional information, please contact me at 202-897-0028 or slee@NASTAD.org.

Sincerely,

Stephen Lee, MD, MBA, DHSM
Executive Director